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Section II. REMARKS

The pending claims in the application are claims 1, 3-7, 10-13, 16 and 19.

The Finality of the First Action on the Merits

In the November 2, 2004 Office Action, the Examiner imposed a final rejection on the subject patent application, even though it is a first action after the filing of a request for continued examination (RCE). According to the Examiner, all claims were drawn to the same invention claimed in the application prior to the entry of the RCE submission and could have been finally rejected on the grounds and art of record in the next Office Action if they had been entered in the application prior to the RCE filing (see, November 2, 2004 Office Action, paragraph bridging pages 5 and 6) (emphasis added).

Further, with regards to the affidavit under 37 C.F.R. §1.132 filed by applicant on July 28, 2004, the Examiner stated:

“[the declaration] include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of non-obviousness of the claimed subject matter and provides no objective evidence thereof.” (see November 2, 2004 Office Action, page 5, lines 15-18) (emphasis added)

Applicant vigorously disagrees with the Examiner's position and requests that the Examiner withdraw the finality of the first action on the merits in view of the following remarks.

It is well established as a matter of law that the burden of proof in establishing a *prima facie* case of obviousness under section 103 is placed on the Patent Office. *Graham v. John Deere Co.*, 38, U.S. 1, 148 U.S.P.Q. 459 (1966). After a *prima facie* case of obviousness has been allegedly established, the burden shifts to the applicant whereby the applicant may introduce evidence, including the so-called Graham secondary considerations, to rebut the Office's *prima facie* case of obviousness. *Perkin Elmer Corp. v. Computervision Corp.*, 221 U.S.P.Q. 669, 675 (Fed. Cir. 1984); *In re Sernaker*, 217 U.S.P.Q. 1, 7-8 (Fed. Cir. 1983).

As stated by the CAFC in *In re Piasecki*, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984):

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"[i]f rebuttal evidence of adequate weight is produced, the holding of prima facie obviousness, being but a legal inference from previously uncontradicted evidence, is dissipated. Regardless of whether the prima facie case would have been characterized as strong or weak, the examiner must consider all of the evidence anew. The process is as stated in *In re Rinehart*, 531 F.2d 1048, 1052, 189 UPSQ 143, 147 (CCPA 1976):

When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. [Though the burden of going forward to rebut the prima facie case remains with the applicant, the question of whether that burden has been successfully carried requires that the entire path to decision be retraced.] An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown ability. * * * Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself" (emphasis added)

In the present matter, applicant discussed in the Background of the Invention section the long-felt need for a stacked plate cross-flow filter that is not vulnerable to misalignment during installation. In addition, applicant submitted the affidavit of Dr. Michael M. Meagher, wherein Dr. Meagher attested:

"[u]nlike other commercially available filtration cassettes, such as the Prostak and the Pellicon, the integral gasketed filtration cassette of the Application does not become misaligned during filtration and as such, does not leak." (see Declaration of Michael M. Meagher, submitted July 28, 2004, point 11) (emphasis added)

In other words, Dr. Meagher attested that the presently claimed filtration cassette is an improvement over other commercially available filtration cassettes thus providing the nexus between the secondary consideration (i.e., long-felt need) and the claimed invention. *See, e.g., Cable Elec. Prods.* 226 U.S.P.Q. 881, 887 (Fed. Cir. 1985).

Accordingly, the declaration of Dr. Meagher was properly submitted in rebuttal to the Examiner's case and should have triggered a consideration of all of the facts available to the Examiner anew. To reiterate, "[f]acts established by rebuttal evidence must be evaluated along with the facts on

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which the earlier conclusion was reached, not against the conclusion itself." *In re Piasecki*, 223 U.S.P.Q. at 788 (emphasis added). "The decision maker must start over." *Id.*

Importantly, upon consideration of the declaration of Dr. Meagher, the Examiner concluded that the declaration affirmed that the "claimed subject matter functions as it was intended to function." The Examiner's statement actually supports the evidence proffered by applicant – that there was a long-felt need for applicant's invention and applicant's invention meets this need. Thus, the declaration is substantial evidence which, contrary to the Examiner's contention, IS "relevant to the issue of non-obviousness."

In conclusion, new grounds of non-obviousness were properly introduced into the record prior to the first examination on the merits of the RCE and the Examiner should not have prematurely issued a final rejection on the first action on the merits. Withdrawal of same is respectfully requested.

Rejection of Claims 1, 3-8, 10-13, 16 and 19, and Traversal Thereof

In the November 2, 2004 Office Action:

claims 1, 3-7, 10-13, 16 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kopf `930 (U.S. Patent No. 5,868,930) in view of Demmer et al. (U.S. Patent No. 5,618,418) (hereinafter Demmer) or Karbachsch et al. (U.S. Patent No. 5,225,080) (hereinafter Karbachsch).

These rejections are traversed and reconsideration of the patentability of the claims is requested in light of the following remarks.

§103(a) Rejection of Claims 1, 3-7, 10-13, 16 and 19 over Kopf `930 in view of Demmer

The Examiner contends that Kopf `930 discloses all of the details of claim 1, including thin gasket layers, but fails to specify the gasket as being bonded to the top and bottom surfaces of the cassette and bonded to and fully encapsulating the side surfaces of the cassette. The Examiner has further stated that Demmer discloses at least one thin gasket layer bonded and fully encapsulating all outer surfaces of the cassette. As such, the Examiner has concluded that:

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"it would have been obvious to have modified the cassette of Kopf so as to have included a thin gasket layer bonded to and fully encapsulating all outer surfaces of the cassette . . . as suggested by Demmer et al. and Karbachsch et al. in order to facilitate assembly of the cassette with adjacent structure." (emphasis added)

Applicant vigorously disagrees.

Kopf '930 relates generally to a cross-flow filtration unit comprising a multiplicity of stacked filtration cassettes, wherein the stacked filtration cassettes comprise membrane filter sheets arranged in a multilaminate, peripherally bonded array, and wherein the membrane filter sheets are alternated with foraminous permeate sheet elements and ribbed retentate channel elements.

As indicated by the Examiner, the relevant teaching of Kopf '930 is the gasket 600 (see Fig. 16 of Kopf '930 reproduced hereinbelow) that permits a "hard shell" filtration cassette (FC), i.e., a filtration cassette comprising an outermost rigid endplate, to be efficiently sealingly mated to a manifold plate of a filter comprising the filtration cassette (see Kopf '930, col. 22, lines 64-67 through col. 23, lines 1-55). It should be noted that there is no motivation or teaching in Kopf '930 that the gasket 600 be permanently affixed to the rigid endplate. Instead, the gasket 600 is expressly taught to be removable.

The only openings in the gasket 600 (in addition to the alignment and mounting openings), are the collection basin openings 622, 624 and the permeate openings 626, 628. In other words, when the gasket (G) is sealingly mated between the endplate (EP) and the manifold plate (MP) (see, e.g., Fig. 17 of Kopf '930, as reproduced hereinbelow for ease of reference), the influent liquid is channeled into and out of the filtration cassette through the collection basin openings 622, 624 and the permeate is channeled out of the filtration cassette through the permeate openings 626, 628. **The influent liquid and permeate do not come in contact with any other part of the gasket material, nor do they mix with one another subsequent to filtration.**

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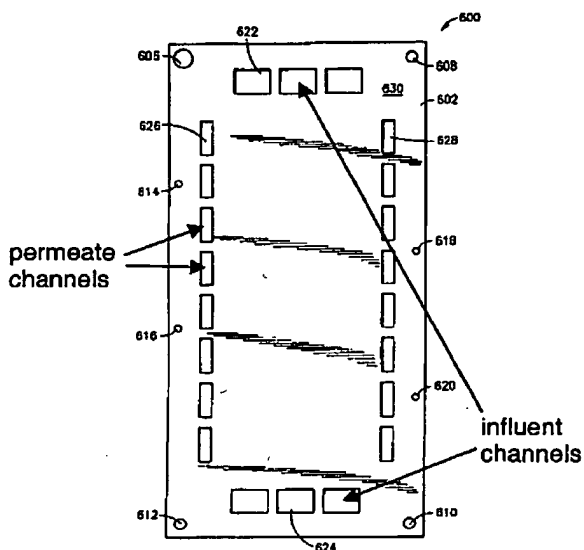


Fig. 16 of Kopf '930

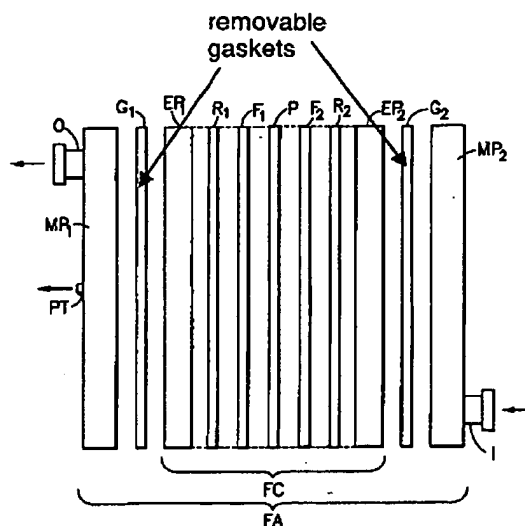
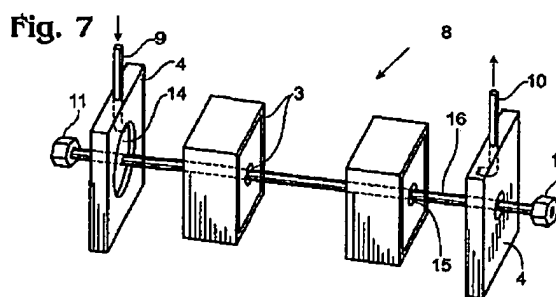
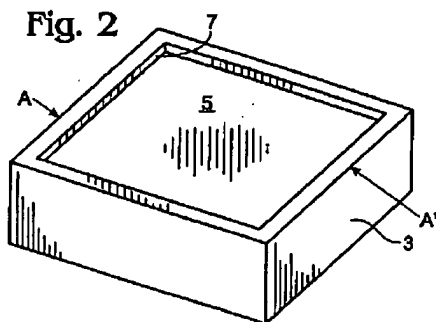


Fig. 17 of Kopf '930

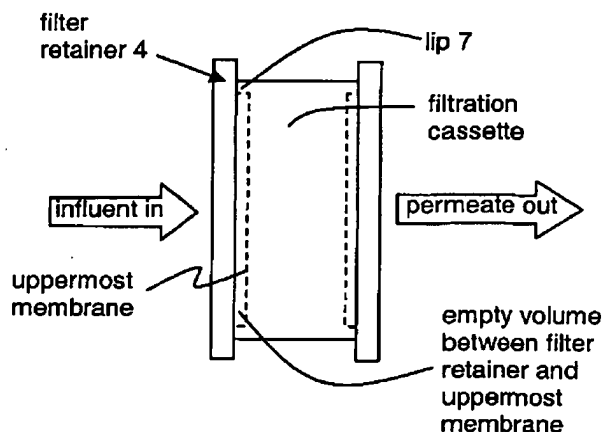
In contrast, Demmer relates to a dead-end filtration unit for the selective separation of fluid substances with adsorbent porous membranes.

The individual adsorbent porous membranes of Demmer are stacked and the edges of the membranes coated with a durable elastic sealant 3 (see, e.g., Fig. 2 of Demmer, reproduced hereinbelow for ease of reference). The elastic sealant overlaps the edges of the adsorbent porous membranes in both the axial and radial directions (see, e.g., the lip 7) (see Demmer, col. 3, lines 31-39). Referring to Fig. 7 of Demmer, reproduced hereinbelow for ease of reference, the lip 7 ensures that a tight seal is formed between the filter cassette and the filter retainer 4 to prevent radial bypass leakage from the filtration unit.



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When the filter cassette of Demmer is positioned between the filter retainers 4, only the lip 7 is sealingly mated to the retainers 4. An area of empty volume exists between the filter retainer and the uppermost membrane of the filter cassette that is circumscribingly defined by the lip 7, as shown schematically hereinbelow.



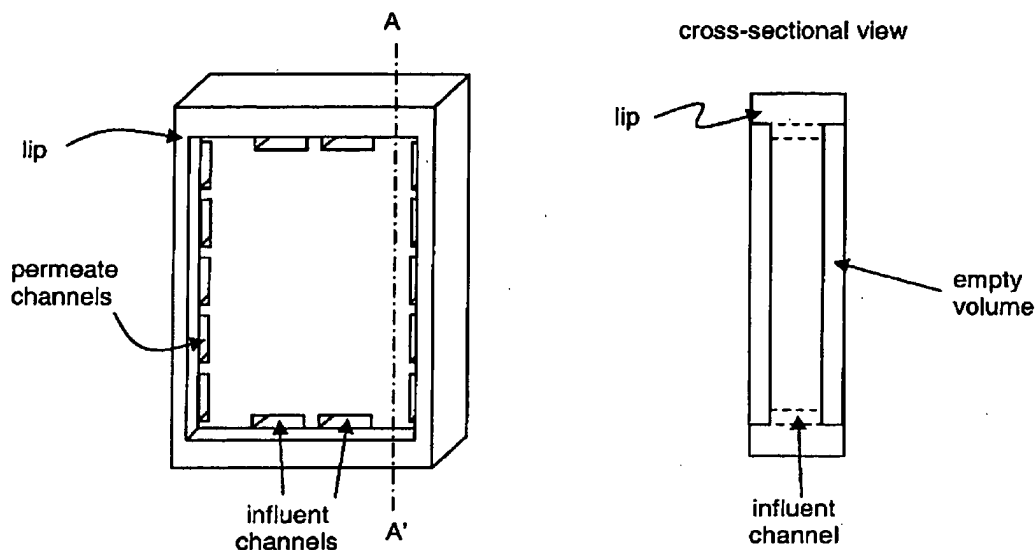
As previously discussed, Kopf `930 discloses cross-flow filtration units while Demmer discloses dead-end filtration units. The filtration methodologies are fundamentally different, requiring different configurations, different maintenance and different energy requirements (see, response to January 21, 2004 Office Action, dated April 21, 2004, pages 17-18). Although the Examiner has repeatedly dismissed this fact, it is reintroduced herein because it is relevant to the lack of combinability of the cited references.

When performing an obviousness evaluation, it is incumbent upon the Examiner to consider the inventions of the cited references in their entireties. See, *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303 (Fed. Cir. 1993), *cert. denied*, 469 U.S. 851 (1984). Certain individual features from the references may not be chosen and merely lumped together as a mosaic in an attempt to meet the features of the rejected claims, while arbitrarily ignoring other teachings disclosed in the references.

The Examiner has suggested that it would be obvious to seal the edges of the Kopf `930 membranes with the encapsulating sealant of Demmer. However, the Examiner is not allowed to arbitrarily pick and choose specific parts of the Demmer sealant for importation. If the encapsulating sealant of Demmer is to be imported into the structure of Kopf `930, the overlap in both the axial and radial directions, i.e., the lip, must be imported as well.

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The net result of this incorporation, based on the Examiner's proposed combination, is illustrated below, both as a perspective view and a cross-sectional view along line A-A' (note, the permeate channels are not shown in the cross-sectional view).



It can be seen that the importation of the Demmer sealant and lip, results in the formation of a recess in the Kopf '930 cassette which defines a large, empty volume, analogous to the empty volume in Demmer. Disadvantageously, the imported lip creates an empty volume in the Kopf '930 cassette that both the influent channels and the permeate channels flow into. In other words, **the Demmer lip destroys the function of the Kopf '930 cassette by allowing permeate to mix with influent in the empty volume created by the lip.**

It is well established in the law that a *prima facie* case of obviousness is not established when prior art teachings are rendered unsatisfactory for their intended purpose upon combination with other cited teachings. See, *In re Gordon*, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

The Examiner can satisfy the burden of showing obviousness of the combination "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references" *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783(Fed. Cir. 1992) (emphasis added).

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Furthermore, although Demmer teaches the use of an encapsulating sealant there is no objective motivation or basis for combining Kopf '930 and Demmer. Locating a reference that teaches an encapsulating layer is not enough – the Examiner still has the burden of providing the objective rationale showing the motivation or basis to combine the cited references. The Examiner has not met this burden by stating that it would be obvious to combine Kopf '930 and Demmer “in order to facilitate assembly of a cassette with adjacent structure” (see November 2, 2004 Office Action, page 3, lines 3-8). In fact, it is not entirely clear what “a cassette with adjacent structure” is, much less how the “cassette with adjacent structure” satisfies the Examiner’s burden.

This compels the conclusion that the rejection is based solely on hindsight, which is impermissible. The courts have made it clear that as Examiner must not use the applicant’s own disclosure as a blueprint to arbitrarily piece together isolated features described in the references (where no teaching or suggestion to combine the references is present) in an attempt to re-create applicant’s claimed invention. For example, recently the CAFC in *Ruiz v. A.B. Chance Co.*, 69 U.S.P.Q.2d 1686, 1690 (Fed. Cir. 2004), reiterated the impermissibility of hindsight, stating that:

“section 103 specifically requires consideration of the claimed invention “as a whole.” Inventions typically are new combinations of existing principles or features. *Envil. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983) (noting that “virtually all [inventions] are combinations of old elements.”). The “as a whole” instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result - often the very definition of invention.” (emphasis added)

It is further noted that Demmer teaches the use of adsorbent porous membranes, wherein the substance to be removed from the influent adsorbs to a coating on the membrane according to a principle analogous to chromatography. Considering Demmer as a whole, the adsorbent membranes of Demmer must also be imported into the cassette of Kopf '930. That said, adsorbent membranes are unsatisfactory in a cross-flow system such as the Kopf '930 cassette because cross-flow filtration fails once substances build up on the membranes, e.g., the substances are adsorbed on the membranes. The advantage of cross-flow filtration is the reduced

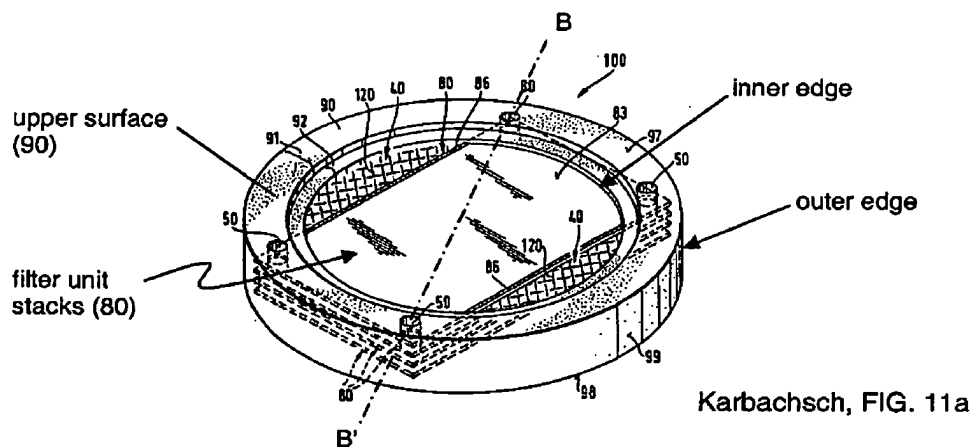
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buildup of substances on the membranes due to the continuous scouring action along the membrane surface by the tangential flow of the influent stream.

Accordingly, the Examiner is respectfully requested to withdraw the rejection of claims 1, 3-7, 10-13, 16 and 19 under 35 U.S.C. §103(a) based on Kopf '930 in view of Demmer, since (1) there is no motivation, suggestion or basis in Kopf '930 or Demmer for their combination, and (2) the combination of Kopf '930 and Demmer would render Kopf '930 unsatisfactory for its intended purpose.

§103(a) Rejection of Claims 1, 3-7, 10-13, 16 and 19 over Kopf '930 in view of Karbachsch

Karbachsch teaches a filtration module 100 wherein at least two multilayer filter units 80 are stacked on top of one another, separated by a spacer 120, and are connected in a leakproof manner by means of an annularly-shaped edge seal 90. A plurality of filtration modules 100 can be stacked upon one another and compressed together in a casing to form a filtration device. Karbachsch's filtration module, as shown in Figure 11a of such reference, is reproduced below.

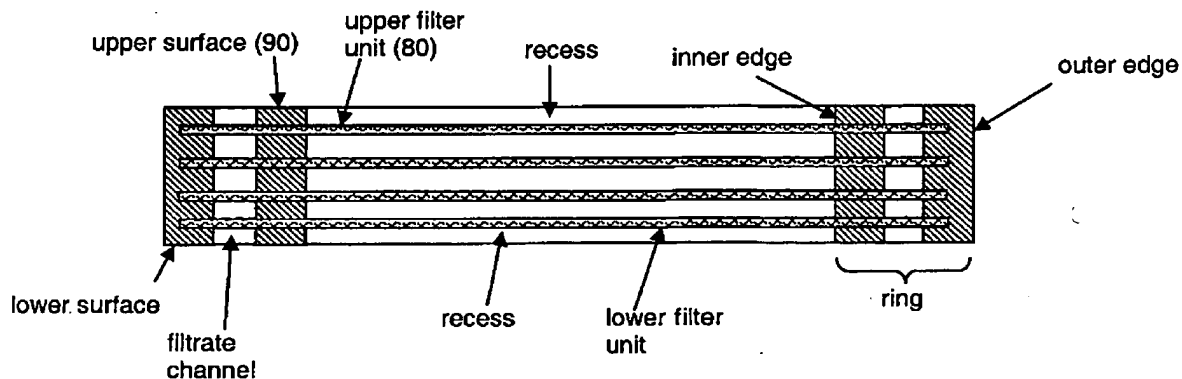


The annularly-shaped edge seal (also referred to as the sealing material ring), of Karbachsch is a ring comprising an upper surface, a lower surface and an outer and inner edge. According to Karbachsch, the annular sealing material fulfills various functions, including:

"by its inner edge surfaces defines the unfiltered material channel [40] and the filter unit [80] stacks." (see Karbachsch, col. 6, lines 29-32) (emphasis added)

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Importantly, the upper surface (and lower surface) of the Karbachsch ring is on a different plane than the upper filter unit 80 (and lower filter unit) and as such, there is a recess in the center of the Karbachsch module (wherein the recess is defined by the circumferential sealing ring), as shown below in the schematic of a cross-section of the Fig. 11a Karbachsch module (wherein the cassette is bisected at line B-B' in the Karbachsch module of Fig. 11a).



As discussed hereinabove, the Examiner is not allowed to focus on specific elements of the cited references and rearrange them to yield applicant's claimed invention, while simultaneously (and arbitrarily) disregarding other relevant teachings of the cited references. In the present case, this is exactly what the Examiner has done – extracted elements from Kopf '930 and Karbachsch to construct applicant's claimed invention in light of applicant's own disclosure. This approach is legally improper.

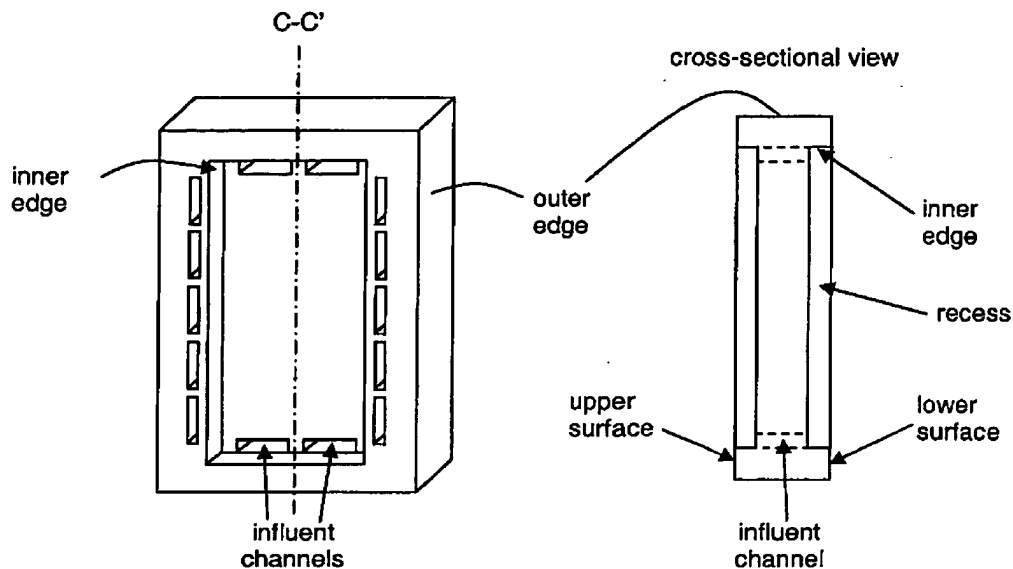
In fact, if the teachings of Kopf '930 and Karbachsch were to be combined, as proposed by the Examiner, Kopf '930 by such modification would be rendered unsatisfactory for its intended purpose, and as such, a *prima facie*, case of obviousness has not been established.

The Examiner has suggested that it would be obvious to import the encapsulating ring of Karbachsch into the cassette of Kopf '930. However, the Examiner must import the whole Karbachsch ring, NOT just the outer edge of the ring. The Examiner is not allowed to arbitrarily pick and choose specific parts of the Karbachsch sealing ring for importation.

The net result of this incorporation, based on the Examiner's proposed combination, is illustrated below, both as a perspective view and as a cross-sectional view (wherein the cassette is bisected at line C-C') (the permeate channels are not shown in the cross-sectional view). Notably, the

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combination of Kopf '930 and Karbachsch differs from that of Kopf '930 and Demmer in that the former includes the permeate openings in the encapsulating ring, consistent with the teaching of Karbachsch.



It can be seen that the importation of the Karbachsch inner edge, which **MUST** correspond to one edge of the unfiltered material channel of Kopf '930 (to be consistent with the teaching of Karbachsch), as well as the Karbachsch upper and lower surfaces, results in the formation of a recess in the Kopf '930 cassette which defines a large, empty volume.

In operation, in addition to passage down the retentate channels of the Kopf '930 cassette, the influent will also flow into this expansive recess. The six planes of the recess are defined by gasket material (or alternatively five planes of gasket material and one plane of manifold material, e.g., metal) and as such, entrance of unfiltered liquid into the recess does not enhance filtration.

More importantly, the cross-sectional area of the influent channels of the modified Kopf '930 cassette will be substantially less than the sum of the inlet areas of the cross flow subchannels (i.e., the retentate sheet openings and the large empty volume openings). In essence, the pressure drop of the overall system is increased. This is a fundamental disadvantage of the prior art that is resolved by the Kopf '930 cassette (see Kopf '930, col. 2, lines 11-20). Why would one skilled in the art combine Kopf '930, which resolved one of the disadvantages of the prior art, with

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Karbachsch to yield a cassette which eliminates said resolution? Clearly, the import of Karbachsch, in its entirety, would render the Kopf '930 filtration cassette unsatisfactory for its intended purpose and as such, a *prima facie* case of obviousness has not been established. *Id.*

Furthermore, where is the objective evidence showing motivation or teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead one to combine the relevant teachings of the Kopf '930 and Karbachsch references? As stated by the court in *In re Dance*, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998):

“[o]ur case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”
(emphasis added)


Again, locating a reference that teaches an encapsulating layer is not enough – the Examiner still has the burden of providing the objective evidence showing the motivation or basis to combine the cited references. The Examiner has not met this burden by stating that it would be obvious to combine Kopf '930 and Karbachsch “in order to facilitate assembly of a cassette with adjacent structure” (see November 2, 2004 Office Action, page 3, lines 3-8).

In sum, there is no motivation or basis in Kopf '930 or Karbachsch for their combination and Kopf '930 would be rendered inoperable upon combination with Karbachsch. The Examiner therefore is respectfully requested to withdraw the rejection of claims 1, 3-7, 10-13, 16 and 19 under 35 U.S.C. §103(a) based on Kopf '930 in view of Karbachsch.

CONCLUSION

Based on the foregoing remarks, claims 1, 3-7, 10-13, 16 and 19 are now in form and condition for allowance. The Examiner therefore is respectfully requested to reconsider and allow such claims.

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